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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,419	10/01/2003	Hirotoshi Adachi	MUR-022-USA-P	5125

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TOWNSEND & BANTA
c/o PORTFOLIO IP
PO BOX 52050
MINNEAPOLIS, MN 55402

EXAMINER	
HOWARD, SHARON LEE	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/674,419	ADACHI ET AL.	
	Examiner	Art Unit	
	Sharon L. Howard	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/1/03,12/23/04,4/11/05*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Receipt of the Remarks, the Preliminary Amendment and the IDS filed on 10/1/03, the notice of change address filed on 12/23/04 and the letter filed on 4/11/05 have been acknowledged. Claims 17-25 are currently amended to more definitely set forth the invention and obviate the rejections. Claims 1-16 having been cancelled in a preliminary amendment. The 112 (second paragraph) rejection is considered withdrawn and moot.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17-25 remain rejected under 35 U.S.C. 102(e) as being anticipated by Sun et al. ('554).

The patent provides an electrotransport, including iontophoresis, delivery system comprising a reservoir containing an ionic drug and an electrode within a low electrolyte aqueous solution and an electrode within the reservoir (see col.1, lines 58-67 and col.2, line 49 to col.3, line 6). The patent includes cationic and anionic agents among the active agents, which may be delivered by the system of the invention (see col.5, line 18 to col.6, line 4) and teaches that buffering agents, such as polymers with acidic functional groups or basic functional groups are placed in the fluid reservoir (see col.12, lines 24-65). The low electrolyte aqueous solution disclosed by the patent is an electrically conductive layer, as claimed by Applicant. With regard

to the limitation in the claims, that the polymer has a polarity selected for controlling pH variations, the patent teaches that polymers, such as Eudragit S or Eudragit E, maintain the pH of the electrode medium (see col.12, lines 38-65). Thus, the patent anticipates claims 17, 18 and 22.

With regard to claims 19-21 and 23-25, the patent discloses copolymers of methacrylic acid and methacrylate, such as Eudragit L and S, an anionic polymers, and includes polymers with amine groups, such as copolymers of dimethylaminoethyl methacrylate and methacrylic acid esters (Eudragit E), among the cationic polymers with basic functional groups (see col.12, lines 24-65).

The compositions disclosed by Sun et al. meet the limitations of claims 17-25 of the instant application, as the patent discloses a system for iontophoresis comprising an electrically conductive layer comprising an ionized active ingredient and a water-swellable polymer. Thus, the patent anticipates the claimed invention.

Claims 17-25 remain rejected under 35 U.S.C. 102(e) as being anticipated by Iga et al. (U.S. Patent 6,322,550).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Iga et al. provides a device for transdermal administration of a GP Iib/IIIa antagonist by iontophoresis, comprising a conductive layer containing a hydrophilic gel (see col.6, lines 40-64). Iga et al. teaches that the gel comprises vinyl resins, aminoacrylmethacrylate (Eudragit E), methacrylic acid copolymers (Eudragit L, Eudragit S), amino acids and their salts (see col.7, line 2 to col.9, line 67). The pH adjusting function claimed by Applicant is inherent. The compositions disclosed by Iga et al. meet the limitations of claims 17-25 of the instant application, as they contemplate a composition comprising a ionized active ingredient and a water-swelling polymer, and a conductive layer comprising said composition. Thus, Iga et al. anticipates the claimed invention.

Response to Arguments

Applicant's arguments filed 10/1/03 have been fully considered but they are not persuasive. Applicant argues that at the outset, it is respectfully urged that Sun, et al. fail to disclose a structure for iontophoresis comprising an electrically conductive layer containing at least one of partially ionized active ingredients and a water swelling polymer having a polarity selected considering the dissociation of the active ingredient for controlling pH variation, and an electrode for supplying electric current to the electrically conductive layer, as now called for in the claims herein.

Applicant also argues that a fair reading of the Sun, et al. reference would lead to the conclusion that the polymer such as Eudragit S or Eudragit E may be used to prevent an increase in the pH of the electrode medium in the fluid reservoir 100 rather than maintaining the pH of the electrode medium.

In contradistinction, in the present invention there is no semipermeable membrane installed between the active agent reservoir and the fluid reservoir as in Sun, et al. Instead, the device of the present invention includes an electrically conductive layer containing at least one of partially ionized active ingredients and a water swelling polymer having a polarity selected considering the dissociation of the active ingredient for controlling pH variations. Sun fails to disclose the structure as now called for in the claims herein and, specifically, the water swelling polymer having polarity selected considering the dissociation of the active ingredient for controlling pH variations in the fluid reservoir. There is no disclosure in Suzuki of an iontophoresis device comprising an electrically conductive layer containing at least one of partially ionized active ingredients and a water swelling polymer having a polarity selected considering the dissociation of the active ingredient for controlling pH variation, and an electrode for supplying electric current to the electrically conductive layer. On the contrary, that teaching or suggestion comes only from the present application and constitutes an important element or aspect of the present invention.

Suzuki et al. fails to anticipate or render unpatentably obvious the subject matter as now called for in the claims herein. Suzuki does not disclose when the use of pH regulators are appropriate or that the use of pH regulators will have any effect whatever. Moreove, Suzuki, et al. fail to disclose that the pH can be controlled with a water swelling polymer having polarity selected considering the dissociation of the active ingredient so as to control pH variation during the electrophoresis.

Applicants respectfully submit that the Examiner's reliance on the Doctrine of Inherency is misplaced in this instance for several reasons. First, the broad disclosure of the addition to the

hydrophilic gel of pH regulators fails to suggest the use of a water swelling polymer having a polarity selected considering the dissociation of the active ingredient for controlling pH variation in an iontophoresis device.

In the present case, Iga, et al. indicate that "PH regulators can be added" to the hydrophilic gel. Thus, it is respectfully submitted that the disclosure of Iga, et al. is insufficient for an inherency rejection since the alleged inherency is not certain. The rejection based on Iga et al. is not a sufficient basis in law to support a rejection based on inherency in view of Ex parte Skinner above.

In response to applicant's arguments "preventing and increasing the pH is controlling with the scope of the claim. The "comprising" language allows antibacterial layers and Suzuki teaches Eudragit E at col.11, line 20. In essence, the same polymer is expected to give the same property. Therefore, the rejections set forth above are maintained for reasons of record. ~~The rejections are obvious over the claims of the instant application and All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.129(a) and could have been finally rejected on the grounds and art of record in the next~~ Office action if they had been entered in the application prior to entry under 37 CFR 1.129(a). Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the submission under 37 CFR 1.129(a). See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Sharon Howard

Sharon Howard

July 6, 2005

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600